OEWG timeline for opening a trial to enrollment, for NCTN Phase 2 (and 1/2) Concepts:

Absolute deadline: 450 days

NCTN Phase 2 (and 1/2) Concepts include the following:

- NCTN phase 2 (or 1/2) Concepts

Phase 2 concept approval stage: 60 days (Day 1 – 60)
Protocol authoring stage: 60 days (Day 60 – 120)
Protocol approval and open to enrollment: 330 days (Day 120 – 450)

(Please see timeline flowchart on next slide.)
Stage 1: Concept approval
Target = 60 days
- Initial Steering Committee review of the Concept
- Consensus Review and conference call with investigators
- NCI approval and if needed, pharmaceutical collaborator approval

Stage 2: Protocol submission
Target = 60 days
- Protocol authoring and submission to the NCI for review

Stage 3: Protocol Approval and Activation
Target = 330 days
- Submission of the protocol to the NCI
- NCI review and conference call with investigators
- Approval of the protocol document by the NCI
- Site finalization: CIRB approval, contract negotiations, FDA review, etc.
- Final approval and activation of the trial

Absolute deadline for opening trial to enrollment is 450 calendar days